

K081105

MAY -9 2008

GE Healthcare

3000 N. Grandview Blvd. W-1140  
Waukesha, WI 53188

## **510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirement of 21 CFR Part 807.87(h).

### **Submitter:**

Name: GE Medical Systems, LLC (GE Healthcare)  
Address: 3000 N. Grandview Blvd., W-1140  
Waukesha, WI 53188

Contact: John Jaeckle  
Regulatory Affairs Program Manager- MI & CT  
Tel: 262-312-7358, Fax: 262-312-7369  
e-mail: John.Jaeckle@med.ge.com

Date Prepared: April 8, 2008

### **PRODUCT IDENTIFICATION**

Name: GE LightSpeed CT750 HD  
(Also known as LightSpeed 8.0 CT Scanner System)

Classification Name: Computed Tomography X-ray System  
21CFR892.1750, 90-JAK

Manufacturer: GE Medical Systems, LLC (GE Healthcare)  
3000 N. Grandview Blvd.  
Waukesha, WI 53188

Future Production may also be accomplished at one of our other registered CT Manufacturing facilities.

Distributor: Same as Manufacturer

Marketed Devices: The GE LightSpeed CT750 HD CT Scanner System (aka GE LightSpeed 8.0) is of comparable type and substantially equivalent to GE's currently marketed Computed Tomography X-ray Systems that comply with the same or equivalent standards and have similar intended uses, such as the previous LightSpeed CT Scanners.

**Predicate Device(s):**

GE LightSpeed 7.1 CT Scanner System (K061817)

**DEVICE DESCRIPTION**

The GE LightSpeed CT750 HD CT Scanner System (aka LightSpeed 8.0) is composed of a gantry, patient table, operator console, computer, and PDU and includes image acquisition hardware, image acquisition and reconstruction software, associated accessories and connections/interfaces to accessories. The GE LightSpeed CT750 HD Scanner System is an evolutionary modification to LightSpeed 7.1 (K061817). It is developed from the hardware platform of LightSpeed 7.1 32/64 slice system by adding new application features that involve changes in hardware, software, firmware, recon, and scan mode.

The GE LightSpeed CT750 HD Scanner System is designed to be a head and whole body CT scanner incorporating the same basic fundamental operating principles and similar Indications for Use. Materials and construction are equivalent to our existing marketed products, which are compliant with UL 60601-1, IEC 60601-1 and associated collateral and particular standards, and 21CFR Subchapter J.

**Indications for Use:**

The GE LightSpeed CT750 HD Computed Tomography X-ray system is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data taken at different angles and planes, including Axial, Cine, Helical (Volumetric), Cardiac, Spectral, and Gated acquisitions for all ages. These images may be obtained either with or without contrast. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories.

This device may include data and image processing to produce images in a variety of trans-axial and reformatted planes. Further the images can be post processed to produce additional imaging planes or analysis results.

The GE LightSpeed CT750 HD CT Scanner System is indicated for head, whole body, cardiac and vascular X-ray Computed Tomography applications.

The device output is a valuable medical tool for the diagnosis of disease, trauma, or abnormality and for planning, guiding, and monitoring therapy.

If the spectral imaging option is included on the system, the system can acquire CT images using different kV levels of the same anatomical region of a patient in a single rotation from a single source. The differences in the energy dependence of the attenuation coefficient of the different materials provide information about the chemical composition of body materials. This approach enables images to be generated at energies selected from the available spectrum to visualize and analyze information about anatomical and pathological structures.

### **Comparison with Predicate:**

The GE LightSpeed CT750 HD Scanner System is developed from the hardware platform of our LightSpeed 7.1 32/64 slice system (K061817). The GE LightSpeed CT750 HD involves changes from the LightSpeed 7.1 system to add new application features that involve changes in hardware, application software, firmware, recon, and scan mode as well as introducing a new 64-slice detector. The GE LightSpeed CT750 HD Scanner System uses virtually the same materials and identical operating principle as our existing marketed product, LightSpeed 7.1, as well as having similar indications for use. We believe the GE LightSpeed CT750 HD Scanner System is of comparable type and substantially equivalent to our currently marketed system listed above and complies with the same or equivalent standards and have the same intended uses.

The GE LightSpeed CT750 HD Scanner System will be certified to comply with the X-ray requirements of 21CFR1020.30 and 1020.33, as well as the safety requirements of UL 60601-1, and IEC 60601-1 and associated collateral and particular standards.

### **Adverse Effects on Health:**

Potential electrical, mechanical and radiation hazards are identified in a risk management summary (hazard analysis) and controlled by:

- System verification and validation to ensure performance to specifications, Federal Regulations, and user requirements.
- Adherence and certification to industry and international standards. (UL/CSA and IEC).
- Compliance to applicable CDRH 21CFR subchapter J requirements.

The device is designed and manufactured under the Quality System Regulations of 21CFR820.

### **Conclusions:**

The GE LightSpeed CT750 HD CT Scanner System is an evolutionary modification to the LightSpeed 7.1 32/64 slice system (K061817). It does not result in any new potential safety risks and performs as well as or better than devices currently on the market. The GE LightSpeed CT750 HD system will be certified to comply with the X-ray requirements of 21CFR 1020.30 and 1020.33, as well as the safety requirements of UL 60601-1, and IEC 60601-1 and associated collateral and particular standards. GE considers the GE LightSpeed CT750 HD CT Scanner System to be equivalent to other marketed devices with similar indications for use and meeting similar standards.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**MAY - 9 2008**

GE Medical Systems, LLC (GE Healthcare)  
% Mr. Jay Y. Kogoma  
Responsible Third Party Official  
Intertek Testing Services  
2307 E. Aurora Rd., Unit B7  
TWINSBURG OH 44087

Re: K081105

Trade/Device Name: GE LightSpeed CT750 HD CT Scanner (aka LightSpeed 8.0)  
Regulation Number: 21 CFR 892.1750  
Regulation Name: Computed tomography x-ray system  
Regulatory Class: II  
Product Code: JAK  
Dated: April 17, 2008  
Received: April 18, 2008

Dear Mr. Kogoma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

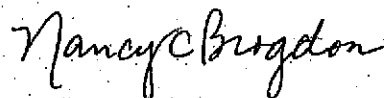
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K081105

Device Name: GE LightSpeed CT750 HD CT Scanner System (aka LightSpeed 8.0)

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Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of Reproductive, Abdominal and  
Radiological Devices

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